Citation:

Dale KS, McAuley KA, Taylor RW, Williams SM, Farmer VL, Hansen P, Vorgers SM, Chisholm AW, Mann JI. Determining optimal approaches for weight maintenance: a randomized controlled trial. *CMAJ*. 2009 May 12;180(10):E39-46.

PubMed ID: 19433812

Study Design:

Randomized Controlled Trial

Class:

A - Click here for explanation of classification scheme.

Research Design and Implementation Rating:

POSITIVE: See Research Design and Implementation Criteria Checklist below.

Research Purpose:

To compare the effectiveness of an intensive program led by health professionals (dietitian and exercise specialist) and and more simple, relatively inexpensive nurse-coordinated program for people attempting to maintain weight loss. Also, to compare two of the most widely recommended nutritional approaches for weight management (high-carbohydrate and high-monounsaturated-fat diets).

Inclusion Criteria:

- Women aged 25-70 years
- Documented, objective evidence (e.g., records from a general practitioner, dietitian or commercial weight-loss program) that they had intentionally lost at least 5% of their initial body weight in the previous 6 months
- Have or have had a BMI $\geq$ 27.

Exclusion Criteria:

- Women with chronic physical or psychiatric illness (including diabetes, gestational diabetes, cardiovascular disease, renal disease, malabsorption disorders, active treatment for cancer and conditions that would prevent them from being physically active
- Taking medications known to affect weight
- Intention to leave the region within the 2 years of recruitment
- Pregnant or intending to conceive within the 2 years of recruitment.

Description of Study Protocol:

Recruitment: Volunteers who responded to notices and newspaper advertisements in Dunedin, New Zealand. Each woman gave written consent for participation.

Design: Randomized controlled trial

Blinding used: Research assistants and laboratory technicians responsible for analysis of diet records and blood samples were unaware of the program and diet groups.

Intervention:

- All participants met individually with a nutritionist to receive instruction on their assigned diet. Participants were give and building-block plan based on their diet allocation (including a daily dietary outline to be placed on their refrigerator) and a book of comprehensive dietary information, including colour-illustrated recipes, guidelines for eating out and samples of weekly menus. Participants also received an individualized exercise program from an exercise consultant. Participants received a weight chart to track their weight changes. Each participant met with the general practitioner after one year to discuss anthropometric changes, clinical findings and laboratory tests. Websites were developed during the first year to enable participants to interact with others in the same dietary intervention group without requiring the involvement of the investigators. During the second year, participants were invited to attend 3 optional group sessions: progressive muscle relaxation and yoga sessions, supermarket tours and diet-specific cooking demonstrations.
- Participants in the nurse-support program also received weigh-in visits every 2 weeks for the duration of the study. On alternate weeks, participants received a phone call from the same nurse to discuss their progress. Support groups were

provided monthly for each of the diet groups. Each participant was paired with a "buddy" who was in the same diet group.
- In the intensive-support group, each participant participated in 11 individualized one-on-one sessions with a nutritionist and exercise trainer at 2 and 6 weeks and 3, 4, 6, 9, 12, 15, 18, 21 and 24 months. Participants were encouraged to attend at least 2 supervised circuit-type training sessions at a private gym each week for the duration of the study, with each session costing $2.
- The high-carbohydrate diet participants were encouraged to eat low-glycemic index foods and plenty of fruits and vegetables and to have moderate intakes of low-fat dairy products, white fish, seafood, lean poultry and lean red meat. The diet was intended to provide 55% total energy from carbohydrates, 15-20% from protein and 25-30% from fat.
- The high-monounsaturated-fat diet was intended to include 25% total energy from protein, 21% from monounsaturated fat and 40% from carbohydrates. Participants were encouraged to consume plenty of fruit and vegetables and to have moderate intake of nuts, avocado and olive and canola oils. They were encouraged to consume low-fat dairy products, white fish, seafood, lean poultry and lean red meat in modest amounts carbohydrate-containing foods, including pasta, rice and cereals.

Statistical Analysis:

- Mixed models were used to analyze the main outcome (weight at years 1 and 2) and secondary outcomes.
- Mixed models was used because it accounts for the underlying covariance between repeated measures.

Data Collection Summary:

Timing of Measurements:

- Measurements were made at baseline and after 1 and 2 years after randomization, except where specified.
- At baseline only, participants completed a questionnaire about their weight, dieting history, eating and exercise behaviors.
- Two years after randomization, participants completed a program-evaluation questionnaire in which they were asked to comment on the usefulness of the program resources and visits, and the frequency of contacts.

Dependent Variables

- Height, weight, BMI
- Waist circumference
- Body composition measured through bioelectrical impedance
- Blood pressure
- Fasting blood samples for measurement of lipids, lipoproteins, glucose and insulin.

Independent Variables

- Support groups (nurse-supported vs. intensive-support program)
- Diet (high-carbohydrate diet vs. high-monounsaturated-fat diet)
- For each participant, dietary intake was recorded over a 3-day period and hunger and satiety were rated using a 7-point scale before and after the 3 main meals. Participants completed the Profile of Mood States self-administered questionnaire, International Physical Activity Questionnaire (Long Last 7 Days Self-administered Format for use with young and middle-aged adults aged 15-69) and the Physical Activity Readiness Questionnaire. The Physical Work Capacity 170 Exercise Test was performed.

Control Variables

- Dietary and exercise advice was provided to all participants

Description of Actual Data Sample:

Initial N: 200 women

Attrition (final N): 174 women (87%)

Age: 25-70 years

Ethnicity: New Zealanders

Other relevant demographics: Not noted

Anthropometrics: Baseline characteristics, including weight loss in the 6 months before recruitment were similar in each of the 4 intervention groups.

Location: Dunedin, New Zealand

Summary of Results:

Key Findings:

- Over 2 years, participants assigned to both diets had reduced weight, BMI, waist circumference, fat mass and systolic blood pressure, with no significant differences between the 2 diets
- During the course of the trial, total and LDL cholesterol were significantly lower among participants in the high-carbohydrate group than among those in the high-monounsaturated-fat group
- Participants' insulin and glucose levels decreased during the study, but there were no significant differences between the diets
- The participants' hunger and satiety scores were unchanged during the study for both diets and there was no significant differences between the groups during the trial.

Differences at follow-up in characteristics of participants in the intensive-support program and nurse-support program

Characteristic	Year 1 Intensive *n*=100	Year 1 Nurse *n*=100	Year 2 Intensive *n*=100	Year 2 Nurse *n*=100	Difference (95% CI)	*p* value
Weight, kg	85.0 ± 14.8	83.3 ± 15.9	84.3 ± 14.4	83.0 ± 15.2	0.1 (-1.8 to 1.9)	0.95
BMI	31.5 ± 5.2	30.9 ± 5.5	31.2 ± 5.1	30.8 ±5.1	0.0 (-0.7 to 0.7)	0.95
Waist, cm	93.3 ± 12.6	90.9 ± 12.8	91.6 ± 12.2	90.1 ± 12.2	-0.5 (-2.4 to 1.4)	0.61
Fat-free mass, kg	48.6 ± 7.3	48.0 ± 7.2	48.3 ± 7.4	47.5 ± 7.1	0.4 (-0.4 to 1.1)	0.36
Fat mass, kg	36.9 ± 9.8	34.6 ± 10.4	36.6 ± 9.8	34.6 ± 9.6	0.3 (-1.2 to 1.8)	0.68
Systolic blood pressure, mm Hg	120 ± 14	117 ± 12	123 ± 14	118 ± 14	1.5 (-1.4 to 4.3)	0.31
Diastolic blood pressure, mm Hg	75 ± 8	74 ± 7	78 ± 8	75 ± 8	0.6 (-0.9 to 2.1)	0.45
Total cholesterol, mmol/L	5.06 ± 0.92	4.84 ± 0.93	5.09 ± 0.98	5.01 ± 0.91	-0.02 (-0.18 to 0.15)	0.86
HDL cholesterol, mmol/L	1.27 ± 0.35	1.31 ± 0.34	1.27 ± 0.38	1.29 ± 0.35	-0.04 (-0.10 to 0.01)	0.13
LDL cholesterol, mmol/L	3.28 ± 0.80	3.02 ± 0.85	3.29 ± 0.84	3.23 ± 0.88	0.02 (-0/12 to 0.17)	0.82
Triglycerides, mmol/L	1.09 ± 0.57	1.11 ± 0.61	1.14 ± 0.60	1.08 ± 0.63	0.01 (-0.09 to 0.11)	0.80
Glucose, mmol/L	4.58 ± 0.45	4.59 ± 0.51	4.61 ± 0.49	4.54 ± 0.49	0.05 (-0.04 to 0.15)	0.29
Insulin, mIU/L	7.74 ± 4.55	7.23 ± 4.06	7.07 ± 5.68	6.59 ± 5.31	1.03 (0.92 to 1.17)	0.60

Differences at follow-up among participants in the high-monounsaturated-fat diet group and the high-carbohydrate diet group

Characteristic	Year 1 High-monounsaturated-fat diet *n*=100	Year 1 High-carbohydrate diet *n*=100	Year 2 High-monounsaturated-fat diet *n*=100	Year 2 High carbohydrate diet *n*=100	Difference (95% CI)	*p* value

Weight, kg	84.8 ± 14.7	83.5 ± 15.9	84.3 ± 14.3	83.0 ± 15.2	0.7 (-1.1 to 2.4)	0.46
BMI	31.4 ± 5.3	31.0 ± 5.4	31.2 ± 5.1	30.8 ± 5.1	0.2 (-0.4 to 0.9)	0.51
Waist, cm	93.0 ± 12.3	91.3 ± 13.1	91.4 ± 11.7	90.3 ± 12.5	0.3 (-1.5 to 2.1)	0.77
Fat-free mass, kg	48.6 ± 7.1	48.0 ± 7.3	48.2 ± 6.9	47.7 ± 7.4	0.4 (-0.3 to 1.1)	0.31
Fat mass, kg	36.0 ± 9.9	35.5 ± 10.5	35.8 ± 9.3	35.4 ± 9.9	0.5 (-0.9 to 2.0)	0.47
Systolic blood pressure, mm Hg	119 ± 12	118 ± 14	121 ± 14	120 ± 14	0.4 (-2.2 to 3.0)	0.75
Diastolic blood pressure, mm Hg	75 ± 7	75 ± 8	76 ± 8	76 ± 8	0.4 (-1.0 to 1.9)	0.56
Total cholesterol, mmol/L	5.08 ± 0.96	4.82 ± 8.87	5.12 ± 0.93	4.98 ± 0.93	0.17 (0.01 to 0.33)	0.04
HDL cholesterol, mmol/L	1.30 ± 0.33	1.28 ± 0.36	1.27 ± 0.37	1.29 ± 0.36	0.01 (-0.04 to 0.06)	0.66
LDL cholesterol, mmol/L	3.27 ± 0.87	3.04 ± 0.77	3.34 ± 0.88	3.18 ± 0.81	0.16 (0.01 to 0.31)	0.039
Triglycerides, mmol/L	1.11 ± 0.59	1.10 ± 0.58	1.11 ± 0.61	1.11 ± 0.62	0.00 (-0.09 to 0.09)	0.98
Glucose, mmol/L	4.58 ± 0.46	4.58 ± 0.49	4.53 ± 0.52	4.62 ± 0.44	-0.06 (-0.14 to 0.03)	0.21
Insulin, mIU/L	7.65 ± 4.15	7.32 ± 4.41	6.41 ± 5.16	7.24 ± 5.61	0.97 (0.87 to 1.09)	0.62

Author Conclusion:

- Women who are sufficiently motivated to join a 2-year study can maintain their weight and, in many instances, further reduce their weight, waist circumference and body fat mass with a simple, inexpensive nurse-support program
- Those following a conventional high-carbohydrate, high-fiber diet achieved similar results to those on a lower-carbohydrate diet that was relatively high in monounsaturated fatty acids
- Improvements in physical fitness and physical activity did not differ during follow-up in the intensive- and nurse-support programs, confirming that costly counseling about physical activity is not an essential component of a program designed to maintain weight loss
- Attendance at the weight-ins was excellent, and many participants reported that the weight-ins and the enthusiastic support provided by the nurse on the occasions and on the telephone were key determinants of their success.

Reviewer Comments:

- *The inclusion of individuals sufficiently motivated to join a 2-year study may be a limitation to the widespread applicability of the findings. The results clearly do not apply to those who have not contemplated the change necessary to facilitate*

weight loss and maintenance

- *Participants did not achieve their dietary targets*
- *The study only compared two of the most popular weight loss diets (high-carbohydrate and high-monounsaturated-fat diets) and therefore results found by this study may not be similar in other calorie/macronutrient restricted diets used for weight-loss.*

Research Design and Implementation Criteria Checklist: Primary Research

Relevance Questions		
1.	Would implementing the studied intervention or procedure (if found successful) result in improved outcomes for the patients/clients/population group? (Not Applicable for some epidemiological studies)	Yes
2.	Did the authors study an outcome (dependent variable) or topic that the patients/clients/population group would care about?	Yes
3.	Is the focus of the intervention or procedure (independent variable) or topic of study a common issue of concern to nutrition or dietetics practice?	Yes
4.	Is the intervention or procedure feasible? (NA for some epidemiological studies)	Yes

Validity Questions		
1.	**Was the research question clearly stated?**	Yes
1.1.	Was (were) the specific intervention(s) or procedure(s) [independent variable(s)] identified?	Yes
1.2.	Was (were) the outcome(s) [dependent variable(s)] clearly indicated?	Yes
1.3.	Were the target population and setting specified?	Yes
2.	**Was the selection of study subjects/patients free from bias?**	Yes
2.1.	Were inclusion/exclusion criteria specified (e.g., risk, point in disease progression, diagnostic or prognosis criteria), and with sufficient detail and without omitting criteria critical to the study?	Yes
2.2.	Were criteria applied equally to all study groups?	Yes
2.3.	Were health, demographics, and other characteristics of subjects described?	Yes
2.4.	Were the subjects/patients a representative sample of the relevant population?	Yes
3.	**Were study groups comparable?**	Yes
3.1.	Was the method of assigning subjects/patients to groups described and unbiased? (Method of randomization identified if RCT)	Yes
3.2.	Were distribution of disease status, prognostic factors, and other factors (e.g., demographics) similar across study groups at baseline?	Yes
3.3.	Were concurrent controls used? (Concurrent preferred over historical controls.)	Yes
3.4.	If cohort study or cross-sectional study, were groups comparable on important confounding factors and/or were preexisting differences accounted for by using appropriate adjustments in statistical analysis?	N/A
3.5.	If case control or cross-sectional study, were potential confounding factors comparable for cases and controls? (If case series or trial with subjects serving as own control, this criterion is not applicable. Criterion may not be applicable in some cross-sectional studies.)	N/A
3.6.	If diagnostic test, was there an independent blind comparison with an appropriate reference standard (e.g., "gold standard")?	N/A

4.	**Was method of handling withdrawals described?**	Yes
4.1.	Were follow-up methods described and the same for all groups?	Yes
4.2.	Was the number, characteristics of withdrawals (i.e., dropouts, lost to follow up, attrition rate) and/or response rate (cross-sectional studies) described for each group? (Follow up goal for a strong study is 80%.)	Yes
4.3.	Were all enrolled subjects/patients (in the original sample) accounted for?	Yes
4.4.	Were reasons for withdrawals similar across groups?	Yes
4.5.	If diagnostic test, was decision to perform reference test not dependent on results of test under study?	N/A
5.	**Was blinding used to prevent introduction of bias?**	Yes
5.1.	In intervention study, were subjects, clinicians/practitioners, and investigators blinded to treatment group, as appropriate?	Yes
5.2.	Were data collectors blinded for outcomes assessment? (If outcome is measured using an objective test, such as a lab value, this criterion is assumed to be met.)	Yes
5.3.	In cohort study or cross-sectional study, were measurements of outcomes and risk factors blinded?	N/A
5.4.	In case control study, was case definition explicit and case ascertainment not influenced by exposure status?	N/A
5.5.	In diagnostic study, were test results blinded to patient history and other test results?	N/A
6.	**Were intervention/therapeutic regimens/exposure factor or procedure and any comparison(s) described in detail? Were interveningfactors described?**	Yes
6.1.	In RCT or other intervention trial, were protocols described for all regimens studied?	Yes
6.2.	In observational study, were interventions, study settings, and clinicians/provider described?	N/A
6.3.	Was the intensity and duration of the intervention or exposure factor sufficient to produce a meaningful effect?	Yes
6.4.	Was the amount of exposure and, if relevant, subject/patient compliance measured?	Yes
6.5.	Were co-interventions (e.g., ancillary treatments, other therapies) described?	Yes
6.6.	Were extra or unplanned treatments described?	Yes
6.7.	Was the information for 6.4, 6.5, and 6.6 assessed the same way for all groups?	Yes
6.8.	In diagnostic study, were details of test administration and replication sufficient?	N/A
7.	**Were outcomes clearly defined and the measurements valid and reliable?**	Yes
7.1.	Were primary and secondary endpoints described and relevant to the question?	Yes
7.2.	Were nutrition measures appropriate to question and outcomes of concern?	Yes
7.3.	Was the period of follow-up long enough for important outcome(s) to occur?	Yes
7.4.	Were the observations and measurements based on standard, valid, and reliable data collection instruments/tests/procedures?	Yes
7.5.	Was the measurement of effect at an appropriate level of precision?	Yes
7.6.	Were other factors accounted for (measured) that could affect outcomes?	Yes
7.7.	Were the measurements conducted consistently across groups?	Yes

8.	**Was the statistical analysis appropriate for the study design and type of outcome indicators?**		Yes
	8.1.	Were statistical analyses adequately described and the results reported appropriately?	Yes
	8.2.	Were correct statistical tests used and assumptions of test not violated?	Yes
	8.3.	Were statistics reported with levels of significance and/or confidence intervals?	Yes
	8.4.	Was "intent to treat" analysis of outcomes done (and as appropriate, was there an analysis of outcomes for those maximally exposed or a dose-response analysis)?	Yes
	8.5.	Were adequate adjustments made for effects of confounding factors that might have affected the outcomes (e.g., multivariate analyses)?	No
	8.6.	Was clinical significance as well as statistical significance reported?	Yes
	8.7.	If negative findings, was a power calculation reported to address type 2 error?	N/A
9.	**Are conclusions supported by results with biases and limitations taken into consideration?**		Yes
	9.1.	Is there a discussion of findings?	Yes
	9.2.	Are biases and study limitations identified and discussed?	Yes
10.	**Is bias due to study's funding or sponsorship unlikely?**		Yes
	10.1.	Were sources of funding and investigators' affiliations described?	Yes
	10.2.	Was the study free from apparent conflict of interest?	Yes